K130006

APR 5 2013

510 K Summary

Submitted By:

Perry Guinn, VP of Quality Assurance and Regulatory Affairs

Cook Biotech Incorporated

1425 Innovation Place

West Lafayette, IN 47906

(765) 807-1942

December 31, 2012

Name of Device:

Trade/Proprietary Name:	Biodesign® Surgisis® Anterior and Posterior Pelvic Floor Grafts
Common/Usual Name:	Surgical Mesh
Classification Name:	Mesh, surgical, non-synthetic, urogynecologic, for pelvic organ prolapse, transvaginally placed
Product Code:	PAI
Classification Number:	21 CFR §878.3300
Device Class:	Class II

Predicate Devices:

Surgisis Sling™ (K992159) manufactured by Cook Biotech Incorporated

Surgisis (K062696) manufactured by Cook Biotech Incorporated

Intended Use:

Cook® Biodesign® Surgisis® Anterior Pelvic Floor Graft is indicated for tissue reinforcement in women with pelvic organ prolapse, for transvaginal repair of anterior and anterior/apical vaginal vault prolapse.

Cook® Biodesign® Surgisis® Posterior Pelvic Floor Graft is indicated for tissue reinforcement in women with pelvic organ prolapse, for transvaginal repair of posterior and posterior/apical vaginal vault prolapse.

Device Description:

The Biodesign® Surgisis® Anterior and Posterior Pelvic Floor Grafts are non-synthetic, non-woven, resorbable layered sheets of natural Extracellular Matrix (ECM) collagen that are pre-configured and can be cut and further shaped by a surgeon to the desired size and shape. The grafts are manufactured from multiple layers of porcine Small Intestinal Submucosa (SIS), an acellular collagenous ECM material derived from porcine small intestine where the serosal, mucosal and muscle layers have been removed. The collagenous material is not cross-linked and is designed to be eventually replaced by the patient's tissue. The shapes of the Biodesign® Surgisis® Anterior and Posterior Pelvic Floor Grafts are specifically designed to meet the clinical needs associated with the device's intended use. The Biodesign® Surgisis® Anterior and Posterior Pelvic Floor Grafts consist of 3 individual grafts: J-PF-ANT-USL, J-PF-ANT-SSL and J-PF-4-POST. J-PF-ANT-USL and J-PF-ANT-SSL are indicated for anterior prolapse repair and J-PF-4-POST is indicated for posterior prolapse repair. The Biodesign® Surgisis® Anterior and Posterior Pelvic Floor Grafts are all supplied sterile and are intended for one time use.

Discussion of Tests and Test Results:

The Biodesign® Surgisis® Anterior and Posterior Pelvic Floor Grafts have undergone and passed all relevant biocompatibility testing (cytotoxicity, sensitization, acute intracutaneous reactivity, acute systemic toxicity, subchronic toxicity and genotoxicity); and performance testing (suture retention strength testing, probe burst strength testing, tensile strength testing, stiffness testing, tear resistance testing and delamination testing). These data support a conclusion that the device is substantially equivalent to the predicate devices. In addition, shelf life testing was also completed to support substantial equivalence. Furthermore, clinical evidence including published clinical data, reinforces the conclusion that the Biodesign® Surgisis® Anterior and Posterior Pelvic Floor Grafts are substantially equivalent to the predicate devices.

Substantial Equivalence:

The subject and predicate device do not have the same Indications for Use statement. The predicate device has a general Indications for Use statement and encompasses a number of different procedures over range of medical disciplines, including vaginal prolapse repair. The subject device is only indicated for transvaginal pelvic organ prolapse repair in specific vaginal compartments. The differences between the Indications for Use statements of the subject and predicate device do not alter the intended therapeutic effect of the device because both the subject and predicate device are used to reinforce soft tissue. Therefore, the subject and predicate device have the same intended use.

The subject and predicate device do not have the same technological characteristics. The new technological characteristics of the subject device include the following:

- The Biodesign Surgisis Grafts are pre-configured to treat specific types of pelvic organ prolapse transvaginally. The Surgisis Sling is rectangular shaped; and therefore, surgeons must modify the Surgisis Sling themselves based the type of repair and a patient's anatomy.
- The Biodesign Surgisis Grafts contain perforations to allow fluid movement through the graft. The Surgisis Sling does not have perforations. The perforations were added to the Biodesign Surgisis Grafts to reduce the risk of seroma formation.
- The Biodesign Surgisis Grafts include resorbable suture to improve handling and prevent delamination. The Surgisis Sling does not include sutures.
- The Biodesign Surgisis Grafts are manufactured differently than the Surgisis Sling. Specifically, the Biodesign Surgisis Grafts undergo additional processing to remove impurities from the SIS material and utilize a different layering technique.

The new characteristics of the subject device could affect safety and effectiveness. Specifically, in regards to safety, the addition of resorbable suture could affect local tissue response. With regard to effectiveness, there is a question of whether the pre-configured mesh is appropriate for its target prolapse repair procedure.

Cook Biotech provided sufficient performance data to assess the effects of the new technological characteristics, including biocompatibility, mechanical performance, and clinical testing, and the performance data demonstrate substantial equivalence of the Surgisis Biodesign Pelvic Floor Grafts to its proposed predicate device.

A substantial equivalence table comparing the Biodesign Surgisis Anterior and Posterior Pelvic Floor Grafts and its predicates is provided on the following page.

Table. Substantial Equivalence Information

Device	Biodesign® Surgisis® Anterior and Posterior Pelvic Floor Grafts	Surgisis™ Sling	Surgisis
Manufacturer	Cook Biotech	Cook Biotech	Cook Biotech
510 (k) Number	K130006	K992159	K062696
Intended Use	Cook® Biodesign® Surgisis® Anterior Pelvic Floor Graft is indicated for tissue reinforcement in women with pelvic organ prolapse, for transvaginal repair of anterior and anterior/apical vaginal vault prolapse. Cook® Biodesign® Surgisis® Posterior Pelvic Floor Graft is indicated for tissue reinforcement in women with pelvic organ prolapse, for transvaginal repair of posterior and posterior/apical vaginal vault prolapse.	For implantation to reinforce soft tissues where weakness exists in the urological, gynecological and gastroenterological anatomy including but not limited to the following procedures: pubourethral support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support, tissue repair and sacrocolposuspension. By providing pubourethral support, the sling may be used for the treatment of urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency	Surgisis is intended for implantation to reinforce soft tissue. The device is intended for one-time use.
Product Code	PAI	FTM	FTM
Material	SIS	SIS	SIS
Thickness	70µm to 600µm (nominal)	70µm to 600µm (nominal)	0.1 to 2.0mm
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
One-time Use	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 5, 2013

Cook Biotech Incorporated
% Mr. Nick X. Wang
Regulatory Specialist
1425 Innovation Place
WEST LAFAYETTE IN 47906

Re: K130006
Trade/Device Name: Biodesign® Surgisis® Anterior and Posterior Pelvic Floor Grafts
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAI
Dated: January 24, 2013
Received: January 29, 2013

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130006

Device Name: Biodesign® Surgisis® Anterior and Posterior Pelvic Floor Grafts

Indications For Use:

Cook® Biodesign® Surgisis® Anterior Pelvic Floor Graft is indicated for tissue reinforcement in women with pelvic organ prolapse, for transvaginal repair of anterior and anterior/apical vaginal vault prolapse.

Cook® Biodesign® Surgisis® Posterior Pelvic Floor Graft is indicated for tissue reinforcement in women with pelvic organ prolapse, for transvaginal repair of posterior and posterior/apical vaginal vault prolapse.

Prescription Use __X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130006